

REMARKS

This Amendment is respectfully submitted in response to the Office Action rendered November 5, 2003.

Claims 27 and 33 have been canceled without prejudice. Claims 26 and 28 have been amended to describe the embodiments applicants wish to present in this application. Applicants respectfully reserve the right to present additional subject matter and embodiments in related patent applications. Claim 29 has been added. The amendments to claims 26 and 28 and newly-added claim 29 find basis in the Specification at p. 2, l. 22-28, p. 3, l. 14 through p. 5, l. 4, p. 6, l. 23-26 and in Example 1 at p. 9, l. 4 through p. 17, l. 2.

The Office Action of November 5, 2003 acknowledged applicants' election with traverse of Group III, claims 27-29. Claims 24-26 were withdrawn from further consideration.

The Office Action of November 5, 2003 rejected claims 28-29 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention on the ground that they depend on a non-existing claim 32. Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims. Applicants have added the phrase "for enhancing the permeation of a retinoid into the skin" in order to clarify the method to which the claims refer and have deleted the reference to "claim 32". Applicants respectfully submit that these amendments clarify the claims and request reconsideration of this rejection.

The Office Action of November 5, 2003 further rejected claim 27 under 35 U.S.C. §102(b) as being anticipated by Simon et al. as well as being anticipated by Hughes et al. In view of the foregoing cancellation of claim 27, applicants respectfully submit that this rejection is moot and request reconsideration thereof.

The Office Action of November 5, 2003 rejected claims 27-29 under 35 U.S.C. §103(a) as being unpatentable over Oblong et al. in view of Simon et al. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Oblong et al. relates to methods of regulating skin appearance with vitamin B₃ compound. Oblong et al. mentions literally hundreds of compounds that may be incorporated into topical products. Oblong et al. *briefly mentions* isoflavones among the many compounds that may be included in the composition [See, e.g., col. 29, l. 13], as

well as "C₃-C₂₂ triglycerides and natural precursors (e.g., soy bean)" [Col. 30, 1.52-53]. Applicants respectfully suggest that this passage most likely refers to triglycerides that may be derived from soy bean, not "non-heat-treated soy products that preserve their active potential". Furthermore, nothing in Oblong et al. would motivate one of ordinary skill in the art to choose any particular ingredients from the hundreds listed, much less to combine specific ingredients in such a way as to enhance the permeation of retinoids into the skin with decreased levels of irritation. reach the compositions of applicants' invention. Applicants further respectfully submit that neither Oblong et al. nor Simon et al. provides motivation for combination with the other to suggest or describe the compositions of applicants' invention.

Simon et al. does not compensate for the insufficiencies of Oblong et al. in leading one of ordinary skill in the art to the compositions and methods of applicants' invention. Simon et al. relates to a composition for combating skin marks and/or aging of the skin containing a saccharide ester of ascorbic acid and a water-soluble sulphonic UVA screening agent. [Simon et al., Abstract]

Simon et al. provides compositions that combat skin marks and/or aging of the skin by the use of UVA-screening agents in conjunction with free radical scavengers. One of ordinary skill in the art would not have looked to the sunscreen formulation art to find compositions that would enhance the penetration of retinoids into the skin—not only do such UVA-screening agents function by resting on the exterior body and absorbing the ultraviolet light before it enters the skin, they have *no* function *within* the skin matrix. Therefore, the Simon et al. compositions would not have been expected to have enhanced permeation characteristics.

Furthermore, nowhere does Simon et al. indicate the use of retinoids or other lipophilic ingredients in the described compositions. Rather, Simon et al. utilizes water-soluble UVA-screening agents. In contrast, certain embodiments of the compositions of applicants' invention utilize a hydrophobic active agent such as retinoids or other vitamins. Thus, Simon et al. does not contemplate the enhanced permeation of lipophilic compounds achieved with the compositions of applicants' invention. While sunscreens may be added to the compositions of applicants' invention for sun protection, the components are not intended to enhance permeation of sunscreens into the skin—this is actually undesirable. Simon et al. neither describes nor suggests the topical permeation-enhancing compositions of applicants' invention. That the hydrophilic polymers and

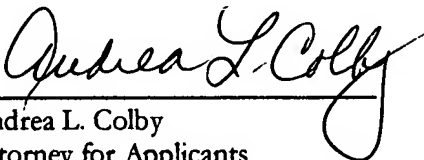
sugars of applicants' compositions enhance permeation of lipophilic vitamins and assist in mitigating irritation is quite surprising in view of Simon et al.

Therefore, applicants respectfully submit that there is no motivation in either cited reference for one of ordinary skill in the art to combine Oblong et al. and Simon et al. to reach the compositions and methods of applicants' invention.

Furthermore, applicants' results demonstrate that the compositions of applicants' invention used in accordance with the claimed method yield surprising results. As set forth in the Specification at page 18 in Table 2, for example, Formulation D, containing Acrylates/C10-30 alkyl Acrylate crosspolymer and AA2G, resulted in an unexpectedly greater total amount of retinol delivered to the skin with a relatively low normalized irritation score and a high ratio of total retinol delivered to the normalized irritation score in comparison with the other formulations tested. The other formulations contained either Acrylates/C10-30 alkyl Acrylate crosspolymer or AA2G alone. One would not have expected these results in view of Oblong et al. and Simon et al. Thus, applicants respectfully request reconsideration of the rejection under 35 U.S.C. §103(a) in view of the foregoing discussion.

In view of the foregoing discussion and amendments to the claims, applicants respectfully request reconsideration of the rejections set forth in the Office Action of November 5, 2003 and respectfully request consideration of the new claim. An early allowance is earnestly solicited.

Respectfully submitted,


Andrea L. Colby
Attorney for Applicants
Reg. No. 30,194

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
February 5, 2004